

**CHILD-RESISTANT PACKAGING
SYSTEM AND METHOD FOR MAKING SAME**

CROSS-REFERENCE TO RELATED APPLICATION

5 This application claims priority to co-pending U.S. provisional Application No. 60/519,601, filed on November 13, 2003, which is entirely incorporated herein by reference.

FIELD OF THE INVENTION

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The present invention relates generally to systems and methods for dispensing and accessing packaged items. More specifically, the present invention is directed to a multi-function child-resistant packaging system.

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BACKGROUND OF THE INVENTION

In the pharmaceutical industry, many types of packaging have been developed for unit doses such as pills, capsules, tablets, chewables, and the like. One type of packaging is the conventional blister pack. In a typical blister pack, a thermoforming technique is 20 used to fabricate a plastic shell containing individual chambers for holding small consumable items such as pills. A backing is then affixed to the back of the shell, thereby enclosing each pill in its own chamber. Individual pills are released from the blister by applying pressure to the pill through the plastic shell. The pill chamber collapses as the pill is driven through the backing at the base of the pill compartment.

That portion of the backing ruptures, and the pill is released from the blister through the resulting opening.

For its combination drug therapy products, a pharmaceutical company may wish to place more than one medication in a blister pack. In certain situations, it may be 5 desirable to package together, in the same blister pack, a first medication that requires a child-resistant container and a second medication that does not require a child-resistant container. However, a survey of the packaging arts does not reveal an apparatus that provides both child-resistant access and free access to respective portions of the same blister pack. Accordingly, there remains in the art a need for a system and method for 10 distributing combinations of medications while restricting access to some medications.

SUMMARY OF THE INVENTION

The problem identified above is addressed by the present invention, aspects of 15 which provide a unit dose packaging system that includes a tray for holding a blister pack containing a plurality of unit dose chambers. The blister pack is divided into a general access zone containing at least one general access unit dose chamber and a restricted access zone containing at least one restricted access unit dose chamber. The general access zone and the restricted access zone are separated by a chamber-free zone. A 20 retaining cap holds the blister pack in the tray. The retaining cap and the tray include therebetween a guide post fitting into a guide slot in the chamber-free zone in the blister. The guide post and the guide slot are positioned in the tray such that when a blister pack is held in the tray by the retaining cap, the blister pack is slidable between a first position in which only the general access zone of the blister is accessible, and a second position in

which both the general access zone and the restricted access zone of the blister are accessible. A child-resistant hinging cap is hingeably mounted to the tray, such that when the hinging cap is in a closed position it locks the blister pack in a first position and when the hinging cap is in an opened position it allows the blister pack to slide to a 5 second position.

As used herein, the terms unit dose and pill includes pills, capsules, caplets, tablets, chewables, and similarly sized items that may suitably be stored in a blister pack. The term "restricted access" includes items that are secured in a child-resistant manner, and the term general access includes items that are not required to be secured in a 10 child-resistant manner.

One embodiment of the present invention provides a system for packaging restricted access and general access items together in a single package. As described in greater detail herein, the restricted access unit dose and the general access unit dose are packaged together in a specially designed blister pack. The blister pack is slideably 15 mounted into a tray, such that the blister pack is slidable between a first position, in which only the general access pills are easily accessible, and a second position, in which both the general access pills and the restricted access pills are more easily accessible.

In another embodiment, a packaging system includes a child-resistant hinging cap for locking the blister pack in a first position. When the child-resistant hinging cap is 20 opened, the blister pack is unlocked and may be slid into a second position to gain access to the restricted access items. After one or more of the restricted access items has been removed from the blister pack, the user may relock the blister pack by sliding the blister

pack back from the second position to the original first position, and reclosing the child-resistant hinging cap.

In another embodiment, a packaging system comprises a tray, a blister pack, a blister retaining cap, and a hinging cap. The blister pack further comprises a general access zone including a plurality of general access chambers, a restricted access zone including a plurality of restricted access chambers, and a chamber-free zone including a guide slot extending into the chamber-free zone. The general access zone and restricted access zone are separated by the chamber-free zone. The retaining cap is coupled to the tray for slideably securing the blister pack within the tray, while the hinging cap is hingeably mounted to the tray to control access to the restricted access zone.

In an embodiment directed to a method for packaging items, one method comprises the steps of packaging items in a blister pack, loading the pack into a tray, affixing a retaining cap to the tray, and hingeably mounting a cap to the tray for controlling access to the restricted access zone. The step of packaging items in a blister pack includes providing a pack with a general access zone including a plurality of general access chambers, a restricted access zone including a plurality of restricted access chambers, and a chamber-free zone including a guide slot axially extending into the chamber-free zone. The step of affixing a retaining cap includes slideably holding the blister pack within the tray.

Thus, a package according to the present invention provides easy access to the general access items while providing a child-resistant system to limit access to restricted access items. Easy access to the general access items is desirable for the elderly, for people with impaired dexterity, or for the convenience of users of medications that are

not dangerous. In addition, the pack frame provides leverage that may be useful in ejecting both the restricted and the general access items out of the blister pack.

It is also contemplated that the present invention is not limited to pharmaceutical-related goods, but is applicable to a plethora of delicate, sensitive, or unique portable goods. Small electronic components, jewelry, foods, expensive and precious articles, and any other item that requires a safe, stable, and portable environment in which to be shipped and stored may find an application with the present invention. Other advantages of the present invention will be apparent from the following description, the accompanying drawings, and the appended claims.

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BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. 1 and 2 show exploded perspective views, from above and below, of an embodiment of the invention.

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FIGS. 3-6 show a series of perspective views illustrating the operation of the hinging cap of FIGS. 1 and 2.

FIGS. 7-9 show a series of perspective views illustrating an alternative embodiment of the present invention.

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DETAILED DESCRIPTION

As required, embodiments of the present invention are disclosed herein; however, it is to be understood that the disclosed embodiments are merely exemplary of the invention that may be embodied in various and alternative forms. The figures are not

necessarily to scale and some features may be exaggerated or minimized to show details of particular components. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a basis for the claims and as a representative basis for teaching one skilled in the art to variously employ the present 5 invention. For purposes of teaching and not limitation, the illustrated embodiments are directed to pharmaceutical packages.

Turning now to the figures, wherein like numerals represent like elements throughout, FIGS. 1 and 2 show exploded perspective views, from above and below, of an embodiment of a packaging system 10 according to the present invention. The 10 packaging system 10 comprises three components: a blister pack 100, a tray 200 into which the blister pack is slidably mounted, and a blister retaining cap 300 that is used to mount the blister pack 100 into the tray 200. In the illustrated embodiment the blister pack 100 is fabricated using a thermoforming technique, and the tray 200 and blister retaining cap 300 are fabricated using an injection molding technique. As understood by 15 those skilled in the art, other fabrication techniques may be used without departing from the scope of the claims.

In the illustrated embodiments, the blister pack 100 is mounted into the tray 200 by a manufacturer, distributor, or pharmacist prior to tendering the package to the end user. Thus, a customer is provided with an assembled pack, in which the blister pack 100 20 has been mounted into the tray 200. It is contemplated that this assembled pack will be disposable. In other embodiments the packaging system 10 is modified so that the tray 200 and blister retaining cap 300 are reusable because a used blister pack 100 may be replaced with a new one.

The blister pack 100 includes a plurality of chambers 102 and 104, and a backing 106. An item such as a pill (not shown) contained in one of the chambers 102, 104 is released from the chamber by applying a downward pressure onto the exterior housing of the selected chamber, causing the chamber to collapse and the item contained therein to 5 be driven against the portion of the backing 106 at the base of the chamber. That portion of the backing 106 ruptures and permits the pill to pass through the resulting opening.

The blister chambers are divided into two groups. A first group of general access chambers 102 contains general access unit doses and a second group of restricted access chambers 104 contains restricted access unit doses. For purposes of teaching and not 10 limitation, the illustrated embodiment includes a 6 x 2 matrix of general access chambers 102, and a 1 x 2 matrix of restricted access chambers 104. It will be understood that the dimensions of these matrices may be freely modified without departing from the scope of the claims. The region of the blister pack 100 containing the general access chambers 102 is referred to herein as the general access zone and the region of the blister pack 100 15 containing the restricted access chambers 104 is referred to herein as the restricted access zone.

As further shown in FIGS. 1 and 2, the blister pack 100 further includes a region 108 between the general access zone and the restricted access zone in which there are no chambers. This region 108 is referred to herein as a chamber-free zone. The 20 chamber-free zone 108 includes a slot 110. Here, the slot 110 is positioned at least partially in both the restricted access zone and the chamber-free zone 108 to define a path having a predetermined length for sliding the blister pack 100 between a first position and a second position.

The tray 200 includes a frame 202 with end walls 204 and 206 and side walls 208 and 210. The tray 200 includes a pair of general access windows 212 and 214 corresponding in position to the general access chambers 102 of the assembled package. The tray 200 further includes a pair of restricted access windows 216 and 218. As 5 described below, when the blister pack 100 is slid into a second position, the restricted access chambers 104 are aligned with the restricted access windows 216 and 218. As shown in FIGS. 1 and 2, the blister pack 100 is oriented in the tray 200 so that the blister backing 106 is positioned between the pill chambers 102 and 104 and the access windows 212, 214, 216 and 218. An item is released from a chamber by exerting pressure on the 10 exterior housing of the chamber in the direction of the access windows corresponding to that chamber, which causes the item to be driven through the blister backing 106 and the corresponding access window 212, 214, 216 and 218. It will be seen from FIG. 2 that the tray frame 202 provides structural support that facilitates the driving of unit doses through the blister backing 106. This aspect of this embodiment may be helpful for users 15 with impaired dexterity. As discussed below, the restricted access chambers 104 are aligned with the restricted access windows 216 and 218 when the blister pack 100 is slid into a second position.

The blister pack 100 is held in the tray 200 by the blister retaining cap 300. As shown in FIGS. 1 and 2, the blister retaining cap 300 includes a base 302 and three walls 20 304, 306, and 308 that together form a hood. This hood forms part of a compartment that houses the restricted access chambers 104 when the blister pack 100 is in a first position. The blister retaining cap 300 further includes a central guide post 310. In the illustrated embodiments, this central guide post 310 is hollow and fits over a corresponding

mounting post 220 on the tray 200. The central guide post 310 may be permanently attached to the mounting post 220 using an adhesive or other suitable technique. If desired, the central guide post 310 may be releasably mounted to the mounting post 220. This latter arrangement would allow the tray 200 and blister retaining cap 300 to be 5 reused with replacement blister packs.

The central guide post 310 is mounted to the mounting post 220 with the central guide post 310 extending through the blister guide slot 110. When mounted together, the upper edges of the blister retaining cap walls 304, 306, and 308 hold the chamber-free portion 108 of the blister 100 against the inner surface of the tray 200.

10 After the blister pack 100 is mounted into the tray 200, the blister pack 100 is slidable in a longitudinal direction. The longitudinal movement of the blister pack 100 within the tray 200 may be determined by the cooperation of the central guide post 310 and the guide slot 110. When the blister pack 100 is in a first position, the central guide post 310 butts up against a first end of the guide slot 110. When the blister 100 is in a 15 second position, the guide post 310 butts up against a second distal end of the guide slot 110. Lateral movement of the blister pack 100 within the tray 200 may be determined by the side walls 208 and 210.

FIGS. 3-6 are a series of perspective views of the packaging system 10, illustrating the structure and operation of a child-resistant hinging cap 250. In the 20 illustrated embodiments, the hinging cap 250 is formed as an integral part of the tray 200 during the fabrication process. However, it is possible to form the child-resistant hinging cap 250 as a separate unit that is subsequently mounted to the tray 200.

FIG. 3 shows the child-resistant hinging cap 250 in a closed position, and FIG. 4 shows the child-resistant hinging cap 250 in an open position, with the blister 100 in a first position. FIG. 5 shows the child-resistant hinging cap 250 in an open position, with the blister pack 100 slid into a second position. FIG. 6 shows a perspective view from 5 below the packaging system 10 with the child-resistant hinging cap 250 in an open position. As shown in FIGS. 3 and 4, the child-resistant hinging cap 250 includes a flap 252 that is attached to an end wall 204 of the tray 200 by a hinge 254. When the hinging cap 250 is in the closed position, it forms a flat surface that is substantially continuous with the base 302 of the blister retaining cap 300.

10 As best shown in FIG. 4, this child-resistant hinging cap 250 includes a pair of ribs 256 and 258 protruding from the interior surface of the flap 252. The ribs 256, 258 are shaped such that they butt up against the restricted access chambers 104 when the hinging cap 250 is in a closed position. In this way, even just one of the ribs 256, 258 locks the blister 100 into a first position when the child-resistant hinging cap 250 is 15 closed. When the child-resistant hinging cap 250 is opened, the ribs 256, 258 are clear of the restricted access chambers 104, allowing the blister 100 to be slid into a second position.

20 As further shown in FIGS. 3 and 4, this child-resistant hinging cap 250 includes a pair of buttons 260 and 262 that protrude outwardly from a pair of resiliently deformable struts 264 and 266. The buttons 260 and 262 are dimensioned and positioned to fit closely within a pair of stirrups 268 and 270 formed in the side walls of the tray. When the child-resistant hinging cap 250 is in a closed position the buttons 260 and 262 protrude outwardly through the stirrups 268 and 270, engaging the edges thereof and

locking the hinging cap 250 in a closed position. As best shown in FIG. 4, the child-resistant hinging cap 250 is opened by pressing the buttons 260 and 262 inward in the direction of arrows 272 and 274 until they are sufficiently clear of the stirrups 268 and 270 to allow the hinging cap 250 to swing open in the direction of arrow 276.

5 It is contemplated that a user of the package will use a thumb and finger of a first hand to press the two buttons 260 and 262 inward, and use the second hand to swing the hinging cap 250 open. In order to facilitate the gripping of the child-resistant hinging cap 250 by the second hand, a semicircular well 312 is provided in the base 302 of the blister retaining cap 300. The hinging cap 250 includes an ear 278 corresponding in position to
10 10 the semicircular well 312 of the blister retaining cap 300. The hinging cap 250 may be reclosed by swinging it downward so that the buttons 260 and 262 once again engage the stirrups 268 and 270. The buttons 260, 262 have a rounded surface allowing the buttons 260, 262 to slide into position without having to use a thumb and finger to inwardly deflect the buttons 260 and 262.

15 As illustrated in FIGS. 5 and 6, the blister pack 100 is slid along the direction of arrow 280 into a second position. In the second position, the restricted access chambers 104 have been slid out from under the protective retaining cap 300 and are now visible and accessible. Further, when the blister pack 100 is in the second position, the restricted access chambers 104 are aligned with restricted access windows 216 and 218, best shown
20 20 in FIG. 6. The unit dose in the restricted access chambers 104 may now be released from the blister pack 100 by applying pressure to the restricted access chambers 104 in the direction of arrow 282. As discussed above, applying pressure in this manner causes the

restricted access chambers 104 to collapse, driving the unit dose contained therein through the backing 106 and out through the windows 216 and 218.

It will be appreciated that the child-resistant hinging cap 250 is child resistant, because it requires the use of both hands and a developed hand-eye coordination to open the hinging cap 250, which children below certain ages generally lack. Even if a child manages to open the hinging cap 250, he or she may find it difficult to slide the blister pack 100 into the second position so as to align the restricted access chambers with the restricted access windows 216 and 218 and then successfully drive a unit dose from its blister 104.

FIGS. 7-9 show a series of diagrams illustrating a further aspect of the invention in which the packaging system 10 is encased in an outer sleeve 400. As shown in FIG. 7, the outer sleeve 400 includes a first open end 402 and a second open end 404 and is shaped to fit closely around the entire packaging system 10. The packaging system 10 may slide out of either end of the outer sleeve 400.

As shown in FIG. 7, when the packaging system 10 is slid out of the first open end 402, the child-resistant hinging cap 250 is exposed without having to completely remove the packaging system 10 from the outer sleeve 400. As shown in FIG. 8, the hinging cap 250 may be opened to provide access to the restricted access chamber 104 of the blister 100. As shown in FIG. 9, when the packaging system 10 is slid out of the second open end 404, the general access chambers 102 of the blister 100 are accessible without having to completely remove the packaging system 10 from the outer sleeve 400.

With regard to one method of packaging items according to the invention, in one step items are packed into a blister pack. The blister pack includes a general access zone

containing at least one general access chamber and a restricted access zone containing at least one restricted access chamber, the general access zone and the restricted access zone being separated by a chamber-free zone. In another step, the blister pack is loaded into a tray. In another step, a blister retaining cap is used to hold the blister pack in the tray.

- 5 The blister retaining cap and the tray include therebetween a central guide post that fits into a guide slot in the chamber-free zone in the blister pack. The central guide post and guide slot are positioned in the tray such that when the blister pack is held in the tray by the blister retaining cap, the blister pack is slideable between a first position, in which only the general access zone of the blister pack is accessible, and a second position in which
- 10 both the general access zone and the restricted access zone of the blister pack are accessible. The blister pack is held in the first position by a child-resistant hinging cap that is hingeably mounted to the tray, such that when the hinging cap is in a closed position it locks the blister pack in a first position and when the hinging cap is in an opened position it allows the blister pack to be slide into a second position.

- 15 While the foregoing description includes details which will enable those skilled in the art to practice the invention, it should be recognized that the description is illustrative in nature and that many modifications and variations thereof will be apparent to those skilled in the art having the benefit of these teachings. It is accordingly intended that the invention herein be defined solely by the claims appended hereto and that the claims be
- 20 interpreted as broadly as permitted by the prior art.